

REMARKS

Applicant submits that the presently amended claims are fully responsive to Examiner's rejections. Specifically, the elements of claim 3 were incorporated into claim 1 in response to Examiner's comment on drafting style and not for reasons related to patentability. As amended, claim 1 describes the inventive method for preventing wound progression and enhancing wound healing in stage 1 and stage 2 wounds by irradiating such wounds with directed non-ablative electromagnetic radiation operating at one or more wavelengths in a range from 193 nm to 10.6 μ m. In addition, claim 13 has been cancelled in response to the Examiner's objections to the lack of antecedent basis in the specification and claim 11 has been cancelled in response to Examiner's 35 U.S.C. s. 112 para. 2 rejection.

Claim Rejections -35 USC s. 102

Claims 1, 8, 11, and 12 were rejected under 35 U.S.C. s. 102(b) as being anticipated by Wolff in US 4,287,554 ("554").

To anticipate the present invention, '554 must teach each and every element as set forth in the claims. MPEP 2131. A close reading of '554 will confirm that the reference does not meet the "every element" requirement and thus does not anticipate the present invention. Moreover, the Examiner has not presented a factual basis or objective technical evidence to support a theory of inherency.

In '554, Wolff teaches an apparatus that emits and directs primarily UVA radiation towards a treatment surface in a disperse field or zone, making it suitable for use as a quick tanning sunlamp. However, '554 further discloses that the apparatus can "also [be used] for medical purposes, for instance, for the treatment of psoriasis." ('554, Col. 11, lines 21-28) But beyond the general assertion that the reference device may be used for "medical purposes," '554 does not teach, imply, or suggest the use of the reference device together with optical fibers for medical purposes nor does '554 teach, imply, or suggest that use of the reference device will prevent wound progression and enhance

healing of stage 1 and stage 2 wounds. As such, '554 fails to teach every element set forth in the claims, and therefore fails to anticipate the present invention.

As used in '554, the phrase "treatment of psoriasis" is a generic indication that, without more, does not teach the elements of the present invention with "sufficient specificity" as required by MPEP 2131. Moreover, the Examiner has not presented a factual basis and/or technical reasoning to support that preventing wound progression and enhancing healing of stage 1 and stage 2 wounds are inherent in and necessarily flow from the teachings of '554. See MPEP 2112. To establish inherency, it is not enough that "a certain result or characteristic may occur or be present" in the reference, instead it is incumbent upon the Examiner to provide objective evidence and/or cogent technical reasoning in support the conclusion of inherency.

As set forth in the claims, the present invention provides a method for preventing progression and enhancing healing of stage 1 and stage 2 wounds, such as those associated with spider bites and other insect bites, bee stings, rashes, poison ivy, poison oak, acne, psoriasis, and eczema. Further, the present inventive method also prevents infection by eradicating bacteria and viral bodies.

As described in the specification, stage 1 wounds are areas of intact skin which are red and inflamed whereas, stage 2 wounds have a noticeable, but superficial breakdown of the skin which gives the appearance of a blister or abrasion. (See page 1, paragraph 0004 of the present application as published.) Psoriasis is a chronic skin disorder that exists in various forms with varying degrees of severity. In its early stages, plaque psoriasis (the most common form of psoriasis) is characterized by raised, thick, dry patches (plaques) on the skin, which are generally covered with scale (keratinized cells) and inflamed. (See Ferri's Clinical Advisor: Instant Diagnosis and Treatment, 2005 ed., Attached)

The amended claims describe a method for treating and healing stage 1 and stage 2 wounds, therefore, the present invention is directed towards psoriasis that is still in the early stages of disease progression, i.e. when disease symptoms are limited to red bumps or scales and are not yet open sores. As a chronic skin disorder with a number of

different manifestations, the specific symptoms associated with the early stages of psoriasis emphasize the generic and unqualified nature of the '554 "medical use" teachings.

Claims 1-4, 6-8, 11, and 12 were rejected under 35 U.S.C. s. 102(e) as being anticipated by Whitehurst in US 6,461,866 ('866).

To anticipate the present invention, '866 must teach each and every element as set forth in the claims. MPEP 2131. A close reading of '866 will confirm that this reference does not meet the "every element" requirement and thus does not anticipate the present invention. Moreover, a factual basis or technical evidence tending to show inherency has not been provided by the Examiner.

Whitehurst discloses a high intensity non-coherent or non-laser light source that uses an optic fiber bundle to deliver light with an intensity greater than 0.075 W/cm^2 and up to 6 W/cm^2 and an output beam having a diameter that is 6mm or less. '866, Cols. 1-2, lines 58-11. The reference also teaches the use of the disclosed non-laser light source in a cosmetic method for the "removal of portwine stains, tattoos or psoriasis" that can be used in conjunction with photoactive drugs. '866, Col. 3, lines 32-39. Specifically, the reference teaches that "for the removal of portwine stains wavelengths of 575 nm may be used" and "for the removal of tattoos wavelengths of 620 nm may be used." '866, Col. 3, lines 41-44. Although '866 characterizes tattoos and portwine stains as "dermatological conditions," tattoos and portwine stains do not constitute wounds that require physical healing. As opposed to stimulating healing or preventing wound progression, '866 instead teaches specific wavelengths of light that will selectively induce the destruction/shrinking of blood vessels in portwine stains (via thermolysis) or the fragmentation/destruction of endogenous pigments used to create and color tattoos. (See Netherlands Organization for Scientific Research, attached)

Moreover, one skilled in the art would not define or characterize tattoos and portwine stains as wounds. Dorland's Medical Dictionary defines a wound as being "injury or damage, usually restricted to those caused by physical means with disruption of normal continuity of structures." (See Dorland's Medical Dictionary, attached) To contrast, a

port-wine stain is a vascular birthmark consisting of superficial and deep dilated capillaries in the skin, causing a reddish or purplish discoloration. (See MedlinePlus Medical Encyclopedia: Port-wine stain, attached). Encyclopedia Britannica defines "tattoo" as "an indelible mark or figure fixed upon the body by insertion of pigment under the skin." (See Encyclopedia Britannica: tattoo, attached)

Thus, unlike the present invention, '866 does not teach or suggest a light source that prevents wound progression or enhances healing of stage 1 or stage 2 wounds. Rather, '866 teaches the destruction of the specific sources of pigmentation found in tattoos and portwine stains in accord with a cosmetic, not a therapeutic (i.e. healing), method. As a result, '866 does not anticipate the present invention because '866 fails to teach, imply, or suggest every element set forth in the claims.

In addition, the Examiner has not presented a factual basis and/or technical reasoning to support that preventing wound progression and enhancing healing of stage 1 and stage 2 wounds are inherent in and would necessarily flow from the teachings of '866. See MPEP 2112. To establish inherency, it is not enough that "a certain result or characteristic may occur or be present" in the reference. The Examiner must provide objective evidence and/or cogent technical reasoning to support the conclusion of inherency.

Claim Rejections under 35 U.S.C. 103

As recited in MPEP 2143 *et seq.*, to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) There must be some suggestion or motivation to modify the teachings of the reference.
- (2) There must be a reasonable expectation of success.
- (3) The references must teach or suggest all the claim limitations.

Claims 2-4 and 6 were rejected under 35 U.S.C. 103(a) as unpatentable in view of ‘554.

The *prima facie* case of obviousness has not been established with respect to ‘554 because the reference does not suggest, teach, or imply the motivation to combine or modify the reference teachings in order to produce the present invention. Moreover, the reference does not disclose all of the elements of the present invention as set out in the claims. In sum, the present invention is not obvious in view of ‘554 because ‘554 fails to suggest the desirability of using electromagnetic radiation and optical fibers to stimulate the physical healing of stage 1 and stage 2 wounds.

As initially discussed on page 5 of this response, Wolff discloses an apparatus with a construction that is especially suited for exposing the face, arms and legs of a user (i.e. the treatment surface) to a disperse field or zone of UV light. To this end, ‘554 teaches an apparatus with a substantially unobstructed opening whereby “the [UV] source and reflector means cooperat[e] to establish ...a high-density radiation field [in the vicinity of the opening].” See ‘554, Col. 2, lines 60-67. Further, the ‘554 apparatus directs radiation to the treatment surface “not only from the front, but also from the sides” of the apparatus. See ‘554, Col. 3, lines 19-24. Thus, ‘554 teaches directly away from the method of the present invention which is described as having “at least one optical fiber connected to a source of electromagnetic radiation” to deliver radiation to the wounded area.

Moreover, beyond the general assertion that the reference device may be used for “medical purposes,” ‘554 does not suggest the use of the reference device in the treatment for stage 1 and stage 2 wounds or that it would be desirable to use the disclosed apparatus for this purpose. Finally, in saying that the ‘554 apparatus can be used for generic medical purposes does not provide a reasonable expectation of success for its use in preventing wound progression or to enhance wound healing in stage 1 and stage 2 wounds. For these reasons, ‘554 fails to establish the obviousness of the present invention.

Claim 5 is rejected under 35 U.S.C. 103(a) in view of Whitehurst ('866)

The *prima facie* case of obviousness has not been established with respect to '866 because the reference does not suggest or imply the motivation to combine or to modify the reference teachings in order to produce the present invention. Moreover, the reference does not disclose all of the elements of the present invention as set out in the claims.

As first discussed on page 7 of this response, Whitehurst teaches directly away from the present invention by disclosing a light source and a cosmetic method for destroying the specific sources of pigmentation found in tattoos and portwine stains. Moreover, Whitehurst neither teaches or suggests modifying the light source or the method to prevent wound progression and/or to enhance healing in stage 1 and stage 2 wounds nor does the removal of portwine stains and tattoos provide a reasonable expectation of success for the prevention of wound progression or enhancing wound healing. Thus, the present invention is not obvious in view of '866 because '866 fails to suggest the desirability of modifying or combining the reference teachings for the treatment and healing of stage 1 and stage 2 wounds arising from spider bites and other insect bites, bee stings, rashes, poison ivy, poison oak, acne, eczema, and early-stage psoriasis.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as unpatentable over Whitehurst ('866) in view of Talmore (US 5,344,433)

The *prima facie* case of obviousness has not been established with respect to '866 in view of '433 because the references do not disclose all of the elements of the present invention as set out in the claims nor do the references suggest, teach, or imply the motivation to combine the reference teachings in order to produce the present invention.

It is well known in the art that the effects of medical lasers are determined by the power density, wavelength, fluence (the total energy delivered), and the duration of irradiation. It is also known that different tissue-types have characteristic effects on irradiation protocols. Indeed, the Examiner correctly points out that "the particular level of radiation power desired would depend upon the application at hand and the particular

skin condition being treated.” In view of the unpredictability of tissue-light interactions and the differences between various wound types, there is no reasonable expectation of success that combining the teachings of ‘866 and ‘433 would prevent wound progression or enhance wound healing in stage 1 and/or stage 2 wounds associated with spider bites and other insect bites, bee stings, rashes, poison ivy, poison oak, acne, and eczema. Without a reasonable expectation of success, the present invention is not made obvious by ‘866 in view of ‘433.

With these changes and remarks, it is believed that the disclosure is now in condition for allowance and reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,



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